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By Laura A. Pettigrew ELI LILLY AND COMPANY Date July 12, 2004

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	James A. Hoffmann & Jirong Lu)	
)	
Serial No.	:	09/744,431)	
)	
International)	Group Art Unit:
Filing Date	:	January 22, 2001)	1647
)	
For	:	FSH and FSH VARIANT)	Examiner:
		FORMULATIONS, PRODUCTS)	R. DeBerry
		AND METHODS)	
)	
Docket No.	:	X-12383M)	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provide a copy of each of the listed documents for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

Applicants request consideration of this information.

Respectfully submitted,

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July 12, 2004



Sheet 1 of 1

FORM PTO 1449 (modified) INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X12383M	Serial No 09/744,431
	Applicants James A. Hoffman, et al.	
	Filing Date January 22, 2001	Group 1647

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T ⁶
	CCB	SERONO Study Report GF 9873, "Evaluation of FSH Formulations claimed in EP-974'359," dated March 22, 2004	
	CCC	European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products (CPMP), "Note for Guidance on Maximum Shelf-life for Sterile Products for Human Use After First Opening or Following Reconstitution," Guidance CPMP/QWP/159/96, 1999.	
	CCD	Gonal-f® RFF Pen, product information	
	CCE	Letter to Ms. Pamela Williamson Joyce regarding Gonal-f® RFF Pen	
	CCF	TOBLER, S.A., et al, "Benzyl Alcohol-Induced Destabilization of Interferon-γ: A Study by Hydrogen-Deuterium Isotope Exchange." Journal of Pharmaceutical Sciences, Vol. 93, No. 6, June 2004.	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. Burden Hours Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.